

Attorney Docket No.: KUZ0030US.NP
Inventors: Toshimitsu et al.
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REMARKS

Claims 1-22 are pending in the instant application. Claims 13-22 have been withdrawn from consideration by the Examiner. Claims 1-12 have been rejected. Claims 1, 9 and 10 have been amended. Claims 8 and 11 have been canceled in light of the amendments to claim 1. Support for these amendments is provided in claims 8 and 11, now canceled, and in teachings of the specification at pages 16-17. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Election/Restriction

Claims 13-22 have been withdrawn from consideration by the Examiner as being directed to an invention that is independent or distinct from the invention originally claimed. The Examiner suggests that these claims would have been subject to a restriction if originally presented due to different search, parameters, burden and that other preparation would produce the same results.

Applicants respectfully traverse this Restriction Requirement.

It is respectfully pointed out that this application is the National Stage of International Application No.

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PCT/JP2004/016091 filed under 35 U.S.C. 371. Claims 1-22 clearly relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they share the same or corresponding special technical feature.

Accordingly, reconsideration of the Restriction and withdrawal of claim 13-22 from the instant application is respectfully requested.

In an earnest effort to be completely responsive, however, and to maintain a clear prosecution history record, Applicants elect to prosecute claims 1-12, with traverse.

II. Rejection of Claims 1-10 under 35 U.S.C. 112, first paragraph - Written Description

Claims 1-10 has been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner suggests that the specification does not support the range of 9-50% range.

Though not conceding to the propriety of the Examiner's rejection, in an effort to move forward prosecution of this case, Applicants have amended claim 1 to remove the language, "9-50% mass".

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Withdrawal of this rejection is therefore respectfully requested.

III. Rejection of Claims 1-10 under 35 U.S.C. 112, second paragraph

Claims 1-10 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner suggests that "mass%" is a relative term that renders the claim indefinite. Though not conceding to the propriety of the Examiner's rejection, in an effort to move forward prosecution of this case, Applicants have amended claim 1 to delete this phrase.

Claims 9 and 10 have also been rejected under 35 U.S.C. § 112, first paragraph, as failing to have antecedent basis for "(meth)acrylic copolymer". Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claims 1, 9 and 10 to provide for antecedent basis. Support for this amendment is provided in teachings of the specification at page 16-17.

Withdrawal of these rejections is therefore respectfully requested.

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IV. Rejection of Claims 1-12 under 35 U.S.C. 102(a)

Claims 1-12 have been rejected under 35 U.S.C. 102(a) as being anticipated by Int'l application Pub. No. WO 2003/013611 of Terahara et al. ("the '611 application").

Applicants respectfully traverse this rejection.

The '611 application fails to disclose at least two limitations of amended claim 1, which recites that the preparation (1) "is capable of achieving a plasma AUC ratio of pergolide or the pharmaceutically acceptable salt thereof to at least one metabolite thereof of 1:0.5 to 1:5", and (2) "the ratio (A/B) of the maximum plasma level (A) of pergolide and/or the pharmaceutically acceptable salt thereof to the plasma level (B) thereof in the next administration is less than 2", support for the latter of which is found, e.g., in claim 8, now canceled.

The case law is clear; to anticipate a claimed invention, the prior art references must teach or suggest all of the particular limitations of the claims. *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970); *In re Royka*, 490 F.2d 981 (CCPA 1974); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) ("The identical invention must be shown in as complete detail as

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is contained in the ... claim."). The '611 application does not expressly disclose these limitations.

Further, contrary to the Examiner's suggestion, the '611 application does not inherently disclose either the claimed pergolide-to-metabolite ratio or the claimed plasma ratio, (A/B). Although identical disclosure of structural components in a cited reference will generally satisfy an examiner's initial burden to make a *prima facie* case of inherency, the Examiner has not met the requirement of providing reasoning to show why these two claimed ratios necessarily flow from the disclosed preparations in the '611 application. "Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection." MPEP § 2112 (I). However, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to

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optimization of conditions, not what was necessarily present in the prior art)" MPEP § 2112(IV). In the instant Office Action, the Examiner specifically fails to show why the claimed limitations in the present application would necessarily flow from the teachings of the '611 application. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)."
Id.

Contrary to the Examiner's assertion, the compositions for the two applications are not nearly identical, and so it does not follow from either fact or technical reasoning that the preparation of the '611 application would necessarily exhibit either of the claimed ratio properties. The '611 application's preparation cannot be used in the context of an ointment or cream, which by contrast, is included as an acceptable dosage form in the present invention. See page 21, lines 21-23 (para. [0019]). Rather, the '611 application requires the use of N-vinyl-2-pyrrolidone, which is unknown outside the patch context. See claim 1 and paragraph [0031]

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of US application Ser. No. 2004/0241240. In particular, the '611 application states that "as a copolymer of N-vinyl-2-pyrrolidone... its species is not particularly limited as long as it is a copolymer in N-vinyl-2-pyrrolidone as one component is copolymerized with another monomer." *Id.* (underlined emphasis added). Applicants submit that these variations in composition cross the boundaries of what properties can be assumed to exist, much less necessarily teaching one of skill, in this uncertain and unpredictable art.

Applicants also respectfully submit that contrary to the Examiner's conclusion, the expected metabolite formation, plasma levels, and AUC ratios of the claims are not inherently met. Because the '611 application requires the use of N-vinyl-2-pyrrolidone, it does not logically follow from technical reasoning or fact that the claimed ratios would necessarily flow from the '611 application's teachings, especially when considering the unpredictable nature of this art and the fact that results will vary from preparation-to-preparation and from drug-to-drug.

Unlike the '611 application, the instant specification shows data for its disclosed formulations in Figures 1-5 and in examples that surprisingly exhibit the undisclosed,

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claimed advantages of suppressing metabolite formation, as expressed in the pergolide-to-metabolite and plasma level ratios set forth in claim 1.

Thus, Applicants respectfully submit that the Examiner's statement that "[a]ll the critical elements are taught by the cited reference" improperly ignores the limitations in the claims. Every limitation must be considered, moreover, without regard to its "gist" or "critical features". "Distilling an invention down to the "gist" or "thrust" of an invention disregards the requirement of analyzing the subject matter "as a whole." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (restricting consideration of the claims to a 10% per second rate of stretching of unsintered PTFE and disregarding other limitations resulted in treating claims as though they read differently than allowed)." MPEP § 2142.02(II); *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970); *In re Royka*, 490 F.2d 981 (CCPA 1974); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) ("The identical invention must be shown in as complete detail as is contained in the ... claim.").

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Thus, claim 1 and claims dependent therefrom are neither taught nor suggested by the '611 application.

Withdrawal of this rejection is therefore respectfully requested.

V. Rejection of Claim 11 under 35 U.S.C. 102(b)

The rejection of claim 11 under 35 U.S.C. 102(b) as being anticipated by Int'l application Pub. No. WO 2003/038139 of Terahara et al. ("the '139 application") and under 35 USC § 102(b) as being anticipated by United States patent number 6,461,636 issued to Arth et al. ("Arth") has been maintained.

Applicants hereby cancel claim 11, thus rendering these rejections moot.

Withdrawal of these rejections under 35 U.S.C. 102(b) is therefore respectfully requested.

VI. Rejection of Claims 1-10 and 12 under 35 U.S.C. 103(a)

Claims 1-10 and 12 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the '139 application.

Applicants respectfully traverse this rejection.

Applicants respectfully submit that this reference does not disclose, suggest, or predict the composition recited in

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claim 1. The '139 application fails to disclose at least two limitations of amended claim 1, which recites that the preparation (1) "is capable of achieving a plasma AUC ratio of pergolide or the pharmaceutically acceptable salt thereof to at least one metabolite thereof of 1:0.5 to 1:5", and (2) "the ratio (A/B) of the maximum plasma level (A) of pergolide and/or the pharmaceutically acceptable salt thereof to the plasma level (B) thereof in the next administration is less than 2", support for the latter of which is found, e.g., in claim 8, now canceled. The case law is clear; prior art references must teach or suggest all of the particular limitations of the claims. *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970); *In re Royka*, 490 F.2d 981 (CCPA 1974); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) ("The identical invention must be shown in as complete detail as is contained in the ... claim."). The '139 application does not teach either of these limitations explicitly or inherently.

Contrary to the Examiner's assertion, the compositions for the two applications are not nearly identical. The '139 application does not disclose an example that incorporates SIS at 10-70%. It requires instead that (1) the content of

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the polymer compound having amino groups is 50% or less by weight based on the whole preparation, (2) a molar ratio of the amino groups in the polymer compound is 0.5 mol of higher per mol of drug, and (3) the content of carboxylic acid and/or salt thereof is 1 to 10 mol per mol of the sum of the drug and amino groups contained in the polymer compound.

Applicants also respectfully submit that contrary to the Examiner's conclusion, the expected metabolite formation, plasma levels, and AUC ratios are not inherently met. Because the '139 application requires that (1) the content of the polymer compound having amino groups is 50% or less by weight based on the whole preparation, (2) a molar ratio of the amino groups in the polymer compound is 0.5 mol of higher per mol of drug, and (3) the content of carboxylic acid and/or salt thereof is 1 to 10 mol per mol of the sum of the drug and amino groups contained in the polymer compound, it does not logically follow from technical reasoning or fact that the claimed ratios would necessarily flow from the '139 application's teachings, especially when considering the unpredictable nature of this art and the fact that results will vary from preparation-to-preparation and drug-to-drug.

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Applicants also submit that the current claims are not obvious in view of Applicants' discovery that "the above problems [e.g., side effects] can be solved by suppressing pergolide metabolite formation or a peak appearance of the plasma level of a pergolide metabolite, and completed the invention as a result of such investigation." See page 8, lines 8-12 (para. [0008]) of the specification. "[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103." *In re Spinnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969)." MPEP § 2141.02 (III).

By way of a clear and persuasive assertion in the specification, Applicants show that the subject matter claimed is not obvious, in part, because it is a solution of a problem that they discovered. "During extensive research to solve problems in the prior arts described above, the inventors surprisingly found out that the above problems [e.g., side effects] can be solved by suppressing pergolide metabolite formation or a peak appearance of the plasma level of a pergolide metabolite, and completed the invention

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as a result of such investigation." See para. [0008] of specification; see also, *id.*, at Table 4 and paras. [0051]-[0052] (Table 4 shows the dramatic reduction in side effects thereby realized by the discovery of this problem. "[S]ide effects accompanied with a metabolite were remarkably reduced because the formation amount of at least one metabolite was extremely low...").

Thus, Applicants respectfully submit that the Examiner's statement that "[a]ll the critical elements are taught by the cited reference" improperly ignores these limitations in the claims. Every limitation must be considered, moreover, without regard to its "gist" or "critical features". "Distilling an invention down to the "gist" or "thrust" of an invention disregards the requirement of analyzing the subject matter "as a whole." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (restricting consideration of the claims to a 10% per second rate of stretching of unsintered PTFE and disregarding other limitations resulted in treating claims as though they read differently than allowed)." MPEP § 2142.02(II); *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970); *In re Royka*, 490 F.2d 981 (CCPA 1974); *Richardson v. Suzuki*

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Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) ("The identical invention must be shown in as complete detail as is contained in the ... claim.").

In addition, "[i]n determining whether the invention as a whole would have been obvious under 35 U.S.C. 103, we must first delineate the invention as a whole. In delineating the invention as a whole, we look not only to the subject matter which is literally recited in the claim in question... but also to those properties of the subject matter which are inherent in the subject matter and are disclosed in the specification. . . Just as we look to a chemical and its properties when we examine the obviousness of a composition of matter claim, it is this invention as a whole, and not some part of it, which must be obvious under 35 U.S.C. 103." *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1977) (emphasis in original) (citations omitted) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The court found the invention as a whole was the ratio of 0.12 and its inherent property that the claimed devices maximized treatment capacity regardless of other variables in the devices. The

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prior art did not recognize that treatment capacity was a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result-effective variable). See also *In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963) ("From the standpoint of patent law, a compound and all its properties are inseparable.").

Obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993). MPEP § 2142.02 (V) (underlined emphasis added). Thus, even if the above-argued limitations are later held inherent, which they are not, claim 1 and dependent claims therefrom would not be obvious over the '139 application because the presence of all of the claimed features could not have been known to one skilled in the art when Applicants invented the claimed invention.

Thus, claim 1 and claims dependent therefrom are not obvious because the claimed invention is neither taught nor suggested by the '139 application, when viewing the invention as a whole.

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Withdrawal of this rejection under 35 U.S.C. 103(a) is therefore respectfully requested.

VII. Provisional Nonstatutory Obviousness-type Double Patenting Rejection

Claims 1-10 and 12 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable (1) over pending claims 1, 7, and 13 of United States patent application Ser. No. 10/486,425 ("the '425 application") in view of the '139 application, and (2) over pending claims 1, 6 and 8 of United States patent application Ser. No. 10/469,612 ("the '612 application") in view of the '139 application.

Applicants respectfully traverse these rejections.

The deficiencies in teachings of the '139 application with respect to obviousness of the instant claimed invention have been discussed in detail in Section VI, supra.

Further, the Examiner has acknowledged that the '425 and '612 applications do not teach the range of pergolides or SIS.

Clearly, neither the combined teachings of the '425 application and the '139 application nor the combined

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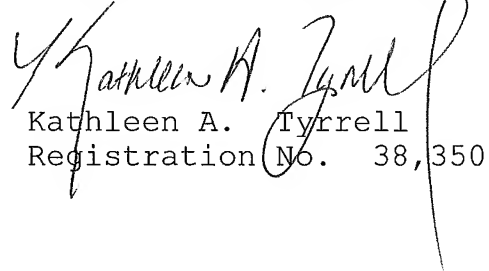
teachings of the '612 application and the '139 application
render obvious the instant claimed invention.

Accordingly, withdrawal of these rejections is
respectfully requested.

VIII. Conclusion

Applicants believe that the foregoing comprises a full
and complete response to the Office Action of record.
Accordingly, favorable reconsideration and subsequent
allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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